May 14, 2024

% Brandie Moore
Regulatory Affairs Specialist II
Canyon Labs
16217 S Bringhurst Dr., Suite 600
Bluffdale, Utah 84065

Re: K232662
Trade/Device Name: BNLE Hydrophilic Jacketed Peripheral Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 30, 2024
Received: April 30, 2024

Dear Brandie Moore:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232662

Device Name

BNLE Hydrophilic Jacketed Peripheral Guidewire

Indications for Use *(Describe)*

The BNLE Hydrophilic Jacketed Peripheral Guidewires are intended to direct a catheter to a desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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10351 Xylon Avenue N., Suite 160
Brooklyn Park, MN 55445

510(k) SUMMARY

Submitter:

Brandie Moore
Regulatory Affairs Specialist II
16217 S Bringhurst Dr., Suite 600
Bluffdale, UT 84065
Phone: (801) 243-0534
Email: Brandie.Moore@canyonlabs.com

Manufacturer:

Biomerics NLE
10351 Xylon Avenue N., Suite 160
Brooklyn Park, MN 55445

DATE PREPARED: 31 August 2023

NAME OF MEDICAL DEVICE:

Proprietary Name:	BNLE Hydrophilic Peripheral Jacketed Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Wire, Guide, Catheter

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DQX
Regulation Number:	21 CFR 870.1330

PREDICATE DEVICE:

Proprietary Name:	Terumo Radifocus Glidewire
Common/Usual Name:	Guidewire
Classification Name:	Wire, Guide, Catheter
510(k) Number:	K152740

DEVICE DESCRIPTION:

The BNLE Hydrophilic Jacketed Peripheral Guidewire is available in 150 cm - 260 cm lengths and in 0.018" – 0.035" diameter ranges. The hydrophilic coated guidewire consists of a nickel-titanium alloy core wire and tungsten infused polyurethane jacket in configurations of wire stiffness and tip shape. The finished guidewire is placed in a dispenser hoop and Tyvek pouch. Five (5) Tyvek pouches are placed into a shelf box with an IFU, and 26 shelf cartons are placed into a shipper box. Labels are placed on the Tyvek pouch and shelf box. The finished product is EO sterilized.

INTENDED USE/INDICATION FOR USE:

Intended Use: The BNLE Hydrophilic Jacketed Peripheral Guidewires are intended to direct a catheter to a desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.

Indications for Use: The BNLE Hydrophilic Jacketed Peripheral Guidewires are intended to direct a catheter to a desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:

Feature	Terumo Radifocus Glidewire K152740 (Predicate Device)	BNLE Hydrophilic Jacketed Peripheral Guidewire (Subject Device)	Discussion
Class	II	II	Identical
Product Code	DQX	DQX	Identical
Regulation (FDA)	21 CFR 870.1330	21 CFR 870.1330	Identical
Indications for Use	The Glidewire is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.	The BNLE Hydrophilic Jacketed Peripheral Guidewires are intended to direct a catheter to a desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.	Identical
Wire Diameter	0.035"	0.018" – 0.035"	Substantially Equivalent, within current legally marketed brackets for this type of device.
Length of Wire	260, 300, 350, 400, and 450cm	150, 180, 260cm	Substantially Equivalent, within current legally

Feature	Terumo Radifocus Glidewire K152740 (Predicate Device)	BNLE Hydrophilic Jacketed Peripheral Guidewire (Subject Device)	Discussion
			marketed brackets for this type of device.
Distal Tip shape	Straight, Angled	Straight, Angled, and J-Tip	Substantially Equivalent, within brackets of predicate device
Wire Type	Standard or Stiff	Standard or Stiff	Identical
Lengths of the Flexible Tip	3 and 5cm	3 cm	Substantially Equivalent, within brackets of predicate device
Jacket Material	Tungsten and Polyurethane	Tungsten and Polyurethane	Identical
Wire Coating	Hydro gel: Hydrophilic polymer (half-ester methyl vinyl ether-maleic anhydride copolymer) Under coat: Polyvinyl chloride	Hydrophilic polymer: Diphenylmethane diisocyanate and Polyvinylpyrrolidone	Though the materials are different performance testing demonstrates that we meet our design requirements and performance is substantially equivalent to the predicate, Terumo Radifocus Glidewire
Core Wire	Nickel-titanium alloy	Nickel-titanium alloy	Identical
Guidewire Inserter	Polyethylene	High Density Polyethylene (HDPE)	Substantially Equivalent, both are biocompatible for their intended use per ISO 10993
Packaging	• Individual package • Unit box • Shipping carton	• Individual package • Unit box • Shipping carton	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Shelf Life	2 years	1 year	Performance testing demonstrates that we meet our design requirements and

Feature	Terumo Radifocus Glidewire K152740 (Predicate Device)	BNLE Hydrophilic Jacketed Peripheral Guidewire (Subject Device)	Discussion
			perform substantially equivalent to the predicate, Terumo Radifocus Glidewire

PERFORMANCE TESTING

The BNLE Hydrophilic Peripheral Jacketed Guidewire was thoroughly tested and verifies that it performs as designed and is suitable for its intended use.

Performance Testing included the following:

- Visual Inspection
- Dimensional
- Device Compatibility
- Tensile
- Torqueability
- Torque Strength
- Kink Resistance
- Flex Resistance
- Fracture Resistance
- Tip Flexibility
- Radiopacity
- Particulate Evaluation / Coating Integrity
- Lubricity and Durability

Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) blood contacting device.

- Cytotoxicity - L929 MEM Elution
- Maximum Sensitization
- Irritation – Intracutaneous Reactivity
- Systemic Toxicity
- Material Mediated Pyrogen
- Hemolysis – Extract and Direct Contact
- Complement Activation Assay
- Thrombogenicity in Canine
- Chemical Characterization

BNLE Hydrophilic Peripheral Jacketed Guidewire met all predetermined acceptance criteria and raised no new concerns regarding safety or efficacy.

CONCLUSION:

The BNLE Hydrophilic Peripheral Jacketed Guidewire has been demonstrated to be substantially equivalent in design, materials, sterilization, principles of operation, performance, and indications for use to the predicate, Terumo Radifocus Glidewire (K152740).